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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Antony Walter Anson

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EXAMINER

WOO, JULIAN W

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/762,223	Applicant(s) ANSON ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51,53,55-64,67,68 and 70-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51,53,55-64,67,68 and 70-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/9/08, 5/12/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 76-78 are rejected under 35 U.S.C. 101 because they claim an artery, an unpatentable part of the human body, as structural part of the invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62, 68, 70-72, and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 62, paragraphs B.a.(3) and B.b(3), the "artery wall," an unpatentable part of the human body, is essentially claimed as structural part of the invention. Also in claim 62, paragraph B.b.(1), it is not certain whether the catheter is a part of the invention; and in paragraph B.b.(4), "the central section" lacks antecedent basis. With respect to base claim 68, "the connection between the elongated members" lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 68, 71, 72, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrild (1,036,229). Harrild discloses, at least in figures 1 and 2, a fixator comprising elongated members (1), each elongated member extending between first and second parts, where the first and second parts (the opposing end portions) are sharpened, where each elongated member has an open configuration (see fig. 1) with first and second parts that are distant and aligned along a common axis, first and second parts adjacently situated with their lengths in abutment (at central portions) and substantially coaxial, and where the fixator has a substantially uniform cross-sectional area as it extends from its first parts to its second parts; and a retaining configuration (see fig. 2), where the first and second parts are closely spaced, where the first and second parts extend from a

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connection (2) between the elongated members, where the each elongated member is biased or bent towards the retaining configuration (after being driven into a medium), where the first and second parts define terminal ends, where the fixator has a substantially uniform cross-sectional area between the non-sharpened portions of the first and second parts when the elongated members are in the open configuration, and where the fixator, when in the retaining configuration is shorter along a direction aligned along the linear axis (i.e., parallel to linear axis) than when in the open configuration. Note: The introductory statement of intended use (“for retaining a graft on an artery”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Harrild’s device, which is capable of being used as claimed if one desires to do so.

7. Claims 51, 53, 55 -61, 63, 70, 73, and 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (6,994,713). Berg et al. discloses, at least in figures 1,13-15 and 18 and in col. 2, lines 3-55; col. 4, lines 4-65; and col. 7, line 14 to col. 8, line 26; a fixator for retaining a graft (30) on an artery, where the fixator includes a plurality of first parts (14 at one end), at least one second part (14 at another end), a resilient member (16) connecting the first and second parts, where the resilient member biases the first and second parts toward each other into a retaining configuration (e.g., see fig. 18), where the first and second parts are moveable into an open configuration as claimed, where only the first and second parts extend from the resilient member, where the resilient member has a cross-sectional area substantially equal to the cross-

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sectional area of the first or second parts in their open configuration, where the first and second parts form arcuate shapes, where the parts are integral, where the fixator has equal numbers of first and second parts, where the device is formed of and linked together by wires (thin, elongated structures, see fig. 13) and from a shape memory alloy (e.g., nitinol), and where each elongated member is normally biased into the retaining configuration.

8. Claims 51, 64, 67, 74, 75, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Shein (3,527,223). Shein discloses a fixator at least in figures 1 and 3-5 and in col. 1, line 67 to col. 2, line 16. With respect to claims 51, 74 and 75, Shein discloses a fixator including a plurality of first parts (24, 26), at least one second part (20, 22), a resilient member (14) connecting the first and second parts, where the resilient member biases the first and second parts toward each other into a retaining configuration (see figs 1, 4, and 5), where the first and second parts are moveable into an open configuration as claimed, where only the first and second parts extend from the resilient member, where the resilient member has a cross-sectional area substantially equal to the cross-sectional area of the first or second parts in their open configuration, and where the first and second parts are respectively adjacently aligned in abutment with each other (at 16 and 18 when, for example, human fingers pinch the first and second parts). With respect to claims 64, 67, and 80, Shein discloses a fixator consisting of elongated members (one elongated member is the combination of 24, portion of 14 and 20 and another member is the combination of 26, portion of 14 and 22), each elongated member extending between first and second parts,

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where the first and second parts are sharpened (inherently along the longitudinal edges of 24, 20, 26, and 22 after “slices” are made at 16 and 18), where each elongated member has an open configuration (see phantom image of 10 in fig. 1 or see fig. 3) with first and second parts that are distant and aligned along a common axis, first and second parts adjacently situated with their lengths in abutment (at 14 and/or as seen in figs. 1 and 3, at 16 and 18) and substantially coaxial, and where the fixator has a substantially uniform cross-sectional area as it extends from its first parts to its second parts; and a retaining configuration (see figs 1 and 5), where the first and second parts are closely spaced, where the each elongated member is biased or bent towards the retaining configuration (after being driven into a medium), where the first and second parts define terminal ends, and where the fixator has a substantially uniform cross-sectional area between the non-sharpened portions of the first and second parts when the elongated members are in the open configuration. Note: The introductory statement of intended use (“for retaining a graft on an artery”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Shein’s device, which is capable of being used as claimed if one desires to do so.

Response to Amendment

9. Applicant's arguments or comments with respect to claims 51, 53, 55-64, 67, 70, and 73-75 have been considered but are moot in view of the new ground(s) of rejection. With respect to arguments regarding the rejection of claims 68, 71, and 72 and based on Harrild: Harrild indeed discloses that only

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first and second parts extend from a connection between the elongate members, where the connection includes element 2, which has centrally-located portions integrated with the first and second parts.

Allowable Subject Matter

10. Claim 62 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a fixator included in a kit, where the fixator includes, inter alia, a plurality of first parts, at least one second part, and a resilient member connecting the first and second parts; and where the kit includes, inter alia, a device for supporting a catheter having a locating member, a plurality of support members, and resilient member, and/or a device for dilating an artery having a locating member, a plurality of dilating members, and a resilient member.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

August 29, 2008